SCHEDULE C

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Federal Court of Canada
Trial Division

Section de première instance de
la Cour fédérale du Canada

Date: 20010202
Docket: T-806-00
Citation: 2001 FCT 16

BETWEEN:

GLAXO GROUP LIMITED
and GLAXO WELLCOME INC.

Applicants

- and -

THE MINISTER OF HEALTH
and APOTEX INC.

Respondents

REASONS FOR ORDER

HANSEN J.

INTRODUCTION

[1] The respondent Apotex Inc. ("Apotex") seeks an order pursuant to paragraph 6(5)(*b*) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166 ("Regulations") dismissing the within application on the grounds that it is frivolous, vexatious, and an abuse of process.

[2] The applicant, Glaxo Group Limited ("Glaxo") is the owner of Canadian Patent Nos. 1,240,313 ("313 Patent") and 1,282,331 ("331 Patent") regarding the medicine cefuroxime axetil. In these reasons, the applicants will be referred to collectively as Glaxo.

[3] By Notice of Allegation dated January 22, 1998, Apotex alleged that no claim for the medicine itself and no claim for the use of the medicine contained in the Glaxo 313 and 331 Patents would be infringed by Apotex's making, using, or selling its cefuroxime axetil tablets.

[4] Glaxo, by Originating Notice of Motion dated March 13, 1998 in Court File No. T-415-98, sought an order prohibiting the Minister of Health ("Minister") from issuing to Apotex a Notice of Compliance ("NOC") with respect to cefuroxime axetil, until the expiry of the above noted patents.

[5] On March 13, 2000, following a hearing on the merits, O'Keefe J. dismissed the application. He concluded that Apotex's allegation of non-infringement was justified.

[6] Subsequent to the service of the January 1998 Notice of Allegation, Apotex made a "minor variation" to its cefuroxime axetil formulation, and as a consequence, served a further Notice of Allegation, again alleging that its revised formulation would not infringe Glaxo's 313 and 331 Patents. Apotex states that the second Notice of Allegation, in all material and

substantive respects, is the same as its earlier Notice of Allegation. As well, the second Notice of Allegation details the "minor variation" in formulation and states that an Abbreviated New Drug Submission ("ANDS") for the medicine was filed with the Minister. The second Notice of Allegation also includes copies of the revised production masters that had been submitted in the ANDS.

[7] In response, Glaxo commenced the within application for an order of prohibition pursuant to the Regulations which Apotex now seeks to have dismissed.

[8] Apotex argues that the new application for an order of prohibition is a re-litigation of the issues previously argued and determined by O'Keefe J., and consequently, is an abuse of the Court's process.

[9] At the outset, it should be noted that, in substance, the grounds alleged in the within application are the same as those in the March 13, 1998 Originating Notice of Motion. Further, in dismissing the first application, O'Keefe J. considered each of the grounds Glaxo raised.

[10] In the within application, the only significant difference is that Apotex voluntarily provided Glaxo with samples of its tablets.

[11] On this motion to dismiss, Glaxo's counsel put forward a number of arguments. In the end, he conceded that what has fundamentally changed, and what distinguishes this from the first proceeding, is that now Glaxo has been in a position to test the tablets and will be able to tender concrete evidence with respect to its assertions.

[12] In the within proceeding and pursuant to subsection 6(7) of the Regulations, Glaxo brought a motion for production of documentation and information contained in Apotex's submission for a Notice of Compliance. Glaxo sought the information to enable them to prepare and test Apotex's tablets and co-precipitate.

[13] Apotex states, that in light of the jurisprudence, Glaxo would likely have been successful on the motion, and given the potential for significant delay while the applicant prepared and tested the tablets and co-precipitate, it voluntarily provided samples. Apotex argues a similar motion could have been brought in the first proceeding.

[14] Glaxo focussed its reply on the lack of a mechanism to require Apotex to produce samples of the medicine. While this is correct, Glaxo could have sought a motion for production of documentation and information in the first proceeding, as it did in the within application.

[15] In *Hoffman-LaRoche Ltd. v. Canada* (1998), 85 C.P.R. (3d) 50, at 55-56 (F.C..T.D.) Rothstein J. stated:

> Is the prohibition application in this case an abuse of the process? I have concluded that it is. What is occurring is repetitious litigation on an issue which has been fully litigated and lost in prior proceedings. To allow the applicants to proceed would be to allow a clear abuse of process.
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> ...
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> The applicants for prohibition are the same, the patent in issue is the same, and the notice of allegations are virtually identical. This litigation is an abuse of process in that it attempts to retry the same issue which has already been determined in three separate proceedings against the applicants.

[16] In *Hofffman-LaRoche, supra,* the factors that led Rothstein J. to conclude there was an abuse of process are analogous to the facts before me. The applicants and the patents are the same in both proceedings, the Notices of Allegation are in all material respects identical, and the issues were fully litigated in the first proceeding. The only distinguishing aspect between the first and current applications is that Glaxo believes it has a better evidentiary basis on which to litigate the issues. Litigants who have already litigated a matter, but lost, should not be permitted to re-litigate because they have acquired new evidence. This, in my view, is an abuse of the Court's process.

[17] For these reasons, the Court grants Apotex's motion to dismiss the application for prohibition in these proceedings, and awards costs to Apotex .

"Dolores M. Hansen"
J.F.C.C.

Ottawa, Ontario
February 2, 2001